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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

52,907

Applicant(s)

LYNSTADAS et al

Examiner

SAUNDERS

Group/Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/24/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 28-64 is/are pending in the application.
- Of the above claim(s) 36-40, 56-59 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 28-35, 41-55, 60-64 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

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The amendment of 9/24/02 has been entered. Claims 28-64 are pending. Claims 28-35, 41-55 and 60-65 are under examination.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 63-65 been renumbered claims 62-64.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The previously stated 112, second paragraph rejections have been overcome by applicant's amendment.

> Applicant is advised that should claim 60 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is noted that applicant's disclosure provides no definitions which would distinguish the scope of "administered" from "applied".

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➤ Applicant is advised that should claim 61 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

➤ Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 64 "said substances" lack antecedent basis in claim 28, which recites a singular "substance". Since claim 28 recites in the singular, it is unclear in claim 64 as to how there can be "mixtures" of more than one substance.

➤ Claims 61 and 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 61 and 63 contain new matter because it is not clear as to where the original disclosure supports applying the substance to the graft. Applicant has pointed to original claims 29-30, but these refer to application to the "graft bed area" or the "site of the graft before application of the graft", as opposed to the graft per se.

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Claims 28, 41-43, 46-47, 50-54, 60, 62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammarstrom et al. (EP 0,263,086), for reasons of record and as explained below.

Applicant considers that the amendment inserting "non-mineralized tissue" has overcome the rejection of record. This does not because the Examples of Hammarstrom show application/administration of the EMD composition to non-mineralized tissue. Note col. 7, lines 48-50 teach the composition was "painted" on the naked root surfaces and covered with a muco-periodontal flap. The soft tissue flap was thus contacted with the composition that had been applied to the root surfaces. Since claim 28 requires no grafting step, this teaching of Hammarstrom et al. properly anticipates.

In addition, Example 7 of Hammarstrom et al. show application of the composition to abdominal muscle, which is a "non-mineralized tissues", this Example thus also anticipates.

New claims 60 and 62 are included in the rejection, since these Examples of Hammarstorm et al. show administration or application of the EMD composition to non-mineralized tissue. New claim 64 is included because the composition used by Hammarstrom et al. is inherently a mixture of active substances

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found in different fractions, as evidenced by Hammarstrom et al. (0,337,967).

> Claims 28, 41-48, 50-51, 54-55, 60, 62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammarstrom et al. (EP-0,337,967), for reasons of record and as explained below.

As in the case of Hammarstrom et al. ('086), Hammarstrom et al. ('967) disclose application of the substance to a naked root surface, which is then covered with a muco-periodontal flap, which is a non-mineralized tissue. See page 7, lines 32-33.

New claims 60 and 62 are included in the rejection. New claim 64 is properly included because the E3 substance that is applied at page 7, lines 32-33 is of itself a mixture of an active high molecular weight fraction and an intermediate molecular weight fraction. See Example 3.

> Claims 28, 41-42, 46-51, 54-55, 60, 62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Mellonig et al. (Int. J. Periodontics restorative Dent. 19, 9-19, 1999), for reasons of record and as explained below.

As in the case of Hammarstrom et al. ('086 and '967), Mellonig et al. show covering of a root surface with an EMD composition. They teach that afterward "every attempt should be made to cover the EMP site with soft tissue". See page 13, col.

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2, lines 9-11. Claim 28 is thus properly anticipated with the same rational applied to Hammarstrom et al.

Additionally, Mellonig et al. teach that "once the wound is closed additional EMD may be applied". Thus would inherently apply the EMD composition to the soft tissue closing the wound. This step anticipates claim 28.

New claims 60, 62 and 64 are rejected following the rational applied to Hammarstrom et al. ('086).

Applicant's urgings filed on 9/24/02 have been considered but are unconvincing.

Claims 28-29, 41-55, 60, 62 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Gestreluis et al. (2002/0169105 A1).

Gestreluis et al. disclose a method of applying the instantly recited enamel matrix substances to a wound area to promote cell growth, revascularization and healing of the wounds in soft tissues. Since instant claim 28 merely requires administration of the enamel matrix substance and no actual transplantation, the claims are properly anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

~~Claims 28-35, 41-55 and 60-65 are rejected under 35 U.S.C.~~

103(a) as being unpatentable over Gestrelus et al.

The conditions for the "taking" of a graft, such as cell growth, vascularization and healing, are the same as those required for the healing of a wound; one would thus have reasonably expected that the enamel matrix compositions shown by Gestrelus et al. as efficacious for wound healing would likewise be efficacious for the healing of soft tissue grafts.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).



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A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-35, 41-55 and 60-65 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 09/258,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 28-29, 41-55, 60, 62 and 65, which merely require administration of the active enamel substance, are claiming at subject matter in common with copending claims 1-53, irrespective of any intended different end result(s). All of the instant claims, as they encompass or are limited to transplantation would have been obvious via the rational applied in the above stated obviousness rejection over Gestreluis et al.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

December 18, 2002

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 / 1644